

**Remarks/Arguments:**

This amendment is in response to the Advisory Action dated September 27, 2007, and the Office Action dated June 11, 2007. Applicants acknowledge receipt of a Notice of Non-Compliant Amendment under 37 CFR § 1.121 with respect to the Amendment filed on Sept. 14, 2007. The non-compliant issues addressed in the Notice have been rectified in this Amendment under 37 CFR § 1.116. All rejections under 35 USC § 112 and 35 USC § 102(e) have been withdrawn. The only remaining rejection is under 35 USC § 102(b) for anticipation by Gorovits, *et al.*

Claims 1 and 7 are currently amended to clarify that the sample comprising protein aggregates has not been exposed to urea in a concentration greater than 3.5M. Support for these amendments may be found in the published specification on page 2, paragraph 0029 ("use of the present invention can substantially or even entirely remove the need for urea..."); page 3, paragraph 37; and pages 7-8, Examples 7 and 8. Example 8 may be found at page 8, paragraph 0084 of the published application (US2005/0020818). No new matter is added by these amendments.

Claims 19 and 20 are added as dependent claims to separately claim methods wherein the sample contains no urea. Support for these claims is found in Examples 7 and 8; page 2, paragraph 0014; and on page 3, paragraph 37. No new matter is added by these amendments.

Gorovits does not teach or disclose that high pressure can increase protein folding in aggregates that have not been exposed to high concentrations of urea, which denatures the protein. As discussed in Applicants' prior response, dated October 30, 2006, the Gorovits methods all include a step of first denaturing or partially unfolding the protein by adding a solution of urea at 3.9M, 6.0M or 8.0M. (See Gorovits, p. 6133-6135).

The methods of amended independent claims 1 and 7 do not include exposing the protein sample to high concentrations of urea prior to applying elevated hydrostatic pressure. Therefore, Gorovits does not teach or disclose all limitations of amended claims 1 and 7 and cannot anticipate these claims. Furthermore, these claims are not made obvious by Gorovits, which does not disclose disaggregation and refolding of proteins that have not been previously

Appln. No.: 10/673,000  
Amendment Dated: October 9, 2007  
Reply to Office Action of September 27, 2007

UOD-154US1

treated with 3.9M or greater concentrations of urea. Therefore, Applicants respectfully request that the Section 102(b) rejections over Gorovits be withdrawn.

Applicants submit that Claims 1 and 7, as amended, new claims 19 and 20, and claims 2-6, and 8-12 are in condition for allowance.

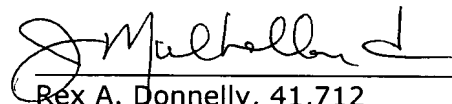
Appln. No.: 10/673,000  
Amendment Dated: October 9, 2007  
Reply to Office Action of September 27, 2007

UOD-154US1

### Conclusion

It is respectfully submitted that the claims are in condition for immediate allowance and a notice to this effect is solicited. The Examiner is invited to phone applicants' attorney if it is believed that a telephonic interview would expedite prosecution of the application.

Respectfully submitted,



Rex A. Donnelly, 41,712  
Joy Mulholland, 47,810  
Attorneys for Applicants

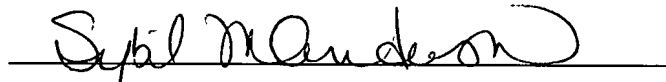
RAD:JM/sma

Dated: October 9, 2007

☐ P.O. Box 980  
Valley Forge, PA 19482  
(610) 407-0700

☒ P.O. Box 1596  
Wilmington, DE 19899  
(302) 778-2500

The Director is hereby authorized to charge or I hereby certify that this correspondence is being deposited v  
Deposit Account No. 18-0350 for United States Postal Service as first class mail, with sufficien  
any additional fees, or any underpayment or cre postage, in an envelope addressed to: Commissioner for Pa  
overpayment in connection herewith. P.O. Box 1450, Alexandria, VA 22313-1450 on: October 9, ;

  
Sybil M. Anderson